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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,486

11/13/2003

David A. Schechter

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09/03/2009

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,486	Applicant(s) SCHECHTER ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received May 18, 2009, have been fully considered by the examiner. The following is a complete response to the May 18, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Objections

Claim 22 is objected to because of the following informalities: "each pocking" (line 13 – newly added subject matter) should read "each pocket". Appropriate correction is required.

Claim Rejections - 35 USC § 103

Claims 1-3, 8 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai et al (6,770,072) in view of the teaching of Yates et al (5,810,811).

Truckai et al disclose a tissue or vessel sealing instrument comprising a housing (not shown) having a shaft (102 - Figure 1) attached thereto and defining a longitudinal

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axis (107). An end effector assembly is attached to the distal end of the shaft and includes first (105a) and second (105B) jaw members attached to the shaft and made from a substantially rigid material. The embodiment of Figures 19A and 19B shows a jaw formation (only the bottom jaw is shown) that includes a rigid material (705A) forming the jaw, and an elastomeric material (726) disposed on the inner surface of the jaw member for contact with tissue. Associated with the elastomeric material, and imbedded therein, are electrodes (730) having a planar tissue contact surface disposed transverse to the longitudinal axis (735) of the jaw. The elastomeric materials is a silicone polymer (col. 16, lines 45-54) as disclosed and claimed by applicant, and would inherently, or at least obviously, have the same properties of compression. Truckai et al also teach that the upper jaw would have the same or similar construction (col. 16, lines 45-48). The only feature not expressly disclosed by Truckai et al is the offsetting of the electrodes when the jaws are closed on tissue.

Yates et al disclose another tissue grasping and sealing device and provide a variety of different electrode configurations for treating tissue. In particular, Figures 17 and 18 show an embodiment where it is preferable to provide the electrode members offset along the length of the jaw members to provide a current flow that is coplanar with the jaw contacting surfaces.

To have provided the Truckai et al sealing device with electrodes offset laterally and/or lengthwise along the length of the jaw member to provide an energy that flows coplanar with the tissue contacting surface would have been an obvious design

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modification for one of ordinary skill in the art since Yates et al fairly teaches it is known to provide such an arrangement of electrodes on an analogous sealing device.

Regarding claim 2, Truckai et al fully disclose the use of silicone and silicone polymers as asserted above, and the use of any other reasonable substitute is deemed an obvious design consideration.

Regarding claim 3, the particular offset distance is also deemed to be an obvious design consideration. Yates et al fail to disclose the specific offset distances, but the examiner maintains that one of ordinary skill in the art would be fully capable, without undue experimentation, of determining optimal spacings for a desired effect. Moreover, applicant's specification is void of any criticality of unexpected result associated with the particular spacing.

Regarding claim 8, the use of similar materials in Truckai et al are deemed to provide a comparable CTI as that set forth in this claim. Moreover, the specific material used and the CTI achieved is deemed a matter of obvious design choice, particularly since applicant's specification again fails to provide any criticality or unexpected result associated with this parameter.

Regarding claims 21 and 23-25, see rejection of claim 1 above. Further, Figures 19A and 19B clearly show the elastomeric material encompassing the electrode leaving only an exposed electrode surface flush with the elastomeric material (as shown in applicant's figures).

Regarding claims 22, 26 and 27, again see the rejection of claim 1. The examiner maintains that the provided offset electrodes are inherently configured to

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result in a uniform temperature distribution. It is further noted that the Truckai et al disclose is particularly directed towards providing a uniform temperature along the jaw surfaces.

Claims 1-5, 7, 8 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al ('811) in view of the teaching of Phan (6,932,816).

Yates et al disclose a device for sealing vessels comprising a housing (16) having a shaft (30) attached thereto and defining a longitudinal axis. An end effector comprising first (32) and second (34) jaws is attached to the distal end of the shaft and the jaws are movable relative to each other. Each jaw member includes electrodes having planar contact surfaces that are offset with respect to each other transverse to the longitudinal axis of the shaft (see Figures 17 and 18. The feature not expressly taught by Yates et al is the provision of an elastomeric material surrounding the electrodes.

Phan discloses another device having jaw members for grasping tissue. In particular, Phan teach that it is advantageous to provide the jaw member with an elastomeric material (106) made from silicone or silicone polymers (col. 6, lines 32-35). The material of Phan is deemed to inherently, or at least obviously, have the same compression properties as applicant's elastomeric material since it is made from similar materials. Moreover, applicant's specification fails to provide any criticality or unexpected result for the particular compression characteristics.

To have provided the Yates et al jaws with an elastomeric material surrounding the electrodes to provide a more flexible contact surface for the jaw members would have been an obvious modification for one of ordinary skill in the art since Phan teaches of the advantages of an electrode embedded in such an elastomeric material for the same purpose in an analogous tissue sealing device.

Regarding claim 2, Phan disclose the use of similar materials, and the use of any other reasonable substitute is deemed an obvious design consideration.

Regarding claim 3, the particular offset distance is also deemed to be an obvious design consideration. Yates et al fail to disclose the specific offset distances, but the examiner maintains that one of ordinary skill in the art would be fully capable, without undue experimentation, of determining optimal spacings for a desired effect. Moreover, applicant's specification is void of any criticality of unexpected result associated with the particular spacing.

Regarding claims 4, 5 and 7, Phan et al fairly disclose the use of temperature sensors (146) for providing feedback information to control energy delivery (col. 10, line 54 to col. 11, line 20). Phan also discloses the means for selecting a desired electrode for activation based on sensed impedance or temperature (col. 11, lines 21-49).

Regarding claim 8, the use of similar materials in Phan is deemed to provide a comparable CTI as that set forth in this claim. Moreover, the specific material used and the CTI achieved is deemed a matter of obvious design choice, particularly since applicant's specification again fails to provide any criticality or unexpected result associated with this parameter.

Regarding claims 21 and 23-25, see rejection of claim 1 above. Further, Figure 8 of Phan clearly shows the elastomeric material encompassing the electrode leaving only an exposed electrode surface for contact with tissue. One of ordinary skill in the art would obviously be capable of using a similar arrangement surrounding the planar electrodes of Yates et al.

Regarding claims 22, 26 and 27, again see the rejection of claim 1. The examiner maintains that the provided offset electrodes are inherently configured to result in a uniform temperature distribution. It is further noted that the Phan fairly teaches providing one or more temperature sensors on the jaw members for maintaining a desired temperature distribution along the jaw members.

Response to Arguments

Applicant's arguments filed May 18, 2009 have been fully considered but they are not persuasive.

Regarding claim 1, applicant contends that the electrodes on each jaw of the Yates et al device are not offset with each other relative to the longitudinal axis of the probe. The examiner disagrees. As shown in Figure 18, reproduced by applicant at page 15 of the response, the electrode labeled (752) on the upper surface is offset laterally from the electrode labeled (751) on the bottom surface. That there may also be an electrode (751 - not labeled) on the bottom surface that is not laterally offset does not mean there is not an offset relationship between at least some of the electrodes. The examiner maintains that Yates et al clearly show an electrode on a second jaw surface that is offset laterally from an electrode on a first jaw surface. Moreover, Yates

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et al specifically disclose a variety of electrode arrangements, and specifically teach in other embodiments (e.g. Figure 13) of providing laterally offset electrodes on first and second jaws. The examiner would further maintain that providing the embodiment of Figure 18 with electrodes that are exclusively offset laterally (i.e. without a counter electrode directly opposing a first electrode on first and second surfaces) would be an obvious alternative mechanism for delivering energy to tissue since Yates et al clearly disclose it is known to use electrodes offset relative to longitudinal axis of the device.

Regarding claims 21 and 23, the examiner maintains the same arguments as with respect to claim 1. Yates et al clearly show an electrode on the second (i.e. lower) jaw that is laterally offset and transversely perpendicular to the longitudinal axis in Figure 18, and also shows such a relationship whereby electrodes are exclusively offset in such a perpendicular direction in the embodiment of Figure 13.

Claim 22 has been amended to recite an electrode disposed in a pocket of the elastomeric material. The examiner maintains that Yates et al clearly show the electrodes disposed in a pocket of the support element as shown in Figure 18. Further, the examiner maintains that Truckai et al also disclose the electrodes located in a pocket in the elastomeric material. As shown in Figures 19A and 19B, the electrodes (730) are recessed within the elastomeric material (726) such that the electrodes are flush with the outer surface of the elastomeric material. It is noted that Figures 7-9 of Truckai et al more clearly show electrodes recessed within the supporting matrix. The examiner maintains that such a recessed electrode construction clearly meets the limitation of an electrode located "in a pocket".

Regarding the combination of the Phan teaching with the Yates et al device, the examiner maintains that the arguments presented above are equally applicable. Again, applicant has asserted that Yates et al fails to disclose the transversely offset electrodes, and the examiner has clearly demonstrated that the Yates et al device clearly shows such a relationship for the electrodes. Yates et al also specifically electrodes formed in pockets, and the combination of the Phan teaching with the Yates et al device would yield a device having electrodes formed in a pocket of an elastomeric material.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
August 30, 2009